

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO: ETHICON WAVE 4 CASES LISTED IN EXHIBIT A	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
---	---

**PLAINTIFFS’ MEMORANDUM OF LAW IN SUPPORT OF MOTION
TO LIMIT THE OPINIONS AND TESTIMONY OF KIM GEISINGER, M.D.**

This Memorandum applies to all Wave 4 Cases as identified in **Exhibit A**, attached to Plaintiffs’ accompanying Motion. Pursuant to Federal Rule of Evidence 702, Plaintiffs hereby seek to limit certain opinions and testimony proffered by Defendant Johnson & Johnson and Ethicon, Inc.’s (hereinafter “Defendants”) expert Kim Geisinger, M.D. on pathology as related to their mesh products. In support of their Motion, Plaintiffs respectfully show the Court as follows:

I. INTRODUCTION

Kim Geisinger, M.D. (“Dr. Geisinger”) is a licensed physician, board certified in “Anatomic Pathology, Clinical Pathology, and Cytopathology.”¹ However, Dr. Geisinger offers certain opinions in these cases that are not supported by reliable methodology or are not supported by reliable application of methodology. Dr. Geisinger has proffered an expert report on pathology as related to Defendants’ mesh products. *See generally* Ex. B. Specifically, Dr. Geisinger opines: “the tissue reaction seen to both Prolene used in Ethicon’s TVT products and

¹ *See Expert Report of Kim Geisinger, M.D.* attached to Plaintiffs’ Motion to Limit the Opinions and Testimony of Kim Geisinger, M.D. (hereinafter the “Motion”) as **Exhibit B**; *see also Curriculum Vitae: Kim Geisinger, M.D.*, attached to Plaintiffs’ Motion as **Exhibit C**.

to Prolene Soft used in Ethicon's pelvic organ prolapse products (e.g., Gynemesh PS, Prolift, and Prosima) is an expected, non-troubling foreign body reaction that leads to good tissue ingrowth." Ex. B at 6. In arriving at these conclusions, Dr. Geisinger sets forth opinions that are: (a) speculative and unsupported by sound methodology.

As such, Dr. Geisinger offers these opinions without utilizing a proper methodology, or without reliably applying methodology as required by Federal Rule of Evidence 702. All of Dr. Geisinger's opinions and testimony suffering from these defects should be excluded or limited.

II. LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403, and 104. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony). The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge. *See Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 588 (1993); *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).

III. ARGUMENT

Dr. Geisinger's medical training in the fields of pathology and cytopathology do not automatically render her opinions on other ancillary issues admissible. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001). Indeed, each individual opinion she offers must satisfy the requirements of the Federal Rules of Evidence to be admissible. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997); *see also Daubert*, 509 U.S. at 579.

Dr. Geisinger's opinions must be based upon reliable and proper methods. *See Coleman v. Union Carbide Corp.*, 2013 WL 5461855, at *17 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible). As this Court has recognized in a related MDL:

Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."

Cisson v. C.R. Bard, Inc., 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). The burden is on the Defendant to show that *each* of Dr. Geisinger's opinions has a reliable foundation based on stated principles and methods. *See Daubert*, 509 U.S. at 597. Opinions which are not the product of reliable principles and methods, or which are not the product of reliable application of principles and methods should be excluded.

A. Dr. Geisinger's Opinions That the Tissue Reaction to Defendants' Mesh Products is an "Expected, Non-Troubling Foreign Body Reaction that Leads to Good Tissue Ingrowth" Should be Excluded.

Dr. Geisinger seeks to offer the following opinion: "the tissue reaction seen to both Prolene used in Ethicon's TVT products and to Prolene Soft used in Ethicon's pelvic organ prolapse products (e.g., Gynemesh PS, Prolift, and Prosima) is an expected, non-troubling foreign body reaction that leads to good tissue ingrowth." Ex. B at 6. Problematic is the basis for this opinion: "I have reviewed a number of surgical pathology specimens from the vagina and perivaginal tissues containing Prolene based meshes that were supplied to me by Butler Snow." *Id.* Dr. Geisinger does not identify: (1) how these particular specimens were selected; (2) the sample size; (3) whether the sample size was large enough to be representative such that reliable conclusions could be drawn therefrom; (4) whether the specimens were opportunistically selected by Defendants' attorneys at Butler Snow; or (5) an identification of which of

Defendants' mesh products were examined (let alone a breakdown of Defendants' products across the sample). *See generally* Ex. B.

These deficiencies render Dr. Geisinger's opinions unreliable insofar as they are based upon her examination of "a number of surgical pathology specimens . . . supplied to [her] by Butler Snow." The reason these opinions are unreliable is somewhat self-evident in that Dr. Geisinger supplies Plaintiffs and this Court with no information regarding her methodology. Moreover, the Court has found these types of opinions to be "unreliable" even when the expert has supplied substantially more information than Dr. Geisinger:

I need not decide whether Dr. Klinge is qualified to offer opinions regarding his examination of explants because his opinions are unreliable. Dr. Klinge states that he examined 485 explants from the mesh collection at the Institute for Pathology, Duren. Of the 485 meshes examined, Dr. Klinge reports that 'a severe fibrosis was seen in > 60% of the TVT-devices . . . But Dr. Klinge does not state how he selected these particular explants, or whether 485 is a large sample size of the Institute's collection. He also offers opinions derived from an analysis of 22 explanted TVT and TVT-O samples . . . Again, Dr. Klinge does not explain how he selected these 22 particular samples. There are no assurances that Dr. Klinge—or plaintiffs' counsel—did not opportunistically choose samples while ignoring others that might have weakened or disproved his theories. In short, there are no indications that Dr. Klinge's analyses of the mesh implants were controlled for error or bias.

In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). Here, Dr. Geisinger presents opinions based on nearly identical deficiencies, but with the added flaw that Dr. Geisinger does not even identify which of Defendants' mesh products were examined; and as such, any and all of Dr. Geisinger's opinions based on this examination should be excluded. *See also In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation*, 2016 WL 4582228, at *5 (S.D. W. Va. Sep. 1, 2016) ("To the

extent that Dr. Iakovlev cannot determine the origin of the slides on which his opinions are based, such opinions are **EXCLUDED** as unreliable”) (emphasis in original).²

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request Dr. Geisinger’s opinions that are: (a) speculative and unsupported by sound methodology be excluded as unreliable under the Federal Rules of Civil Procedure and applicable case law.

Specifically, Dr. Geisinger should be prevented from opining: “the tissue reaction seen to both Prolene used in Ethicon’s TVT products and to Prolene Soft used in Ethicon’s pelvic organ prolapse products (e.g., Gynemesh PS, Prolift, and Prosima) is an expected, non-troubling foreign body reaction that leads to good tissue ingrowth,” Ex. B at 6, (as well as all other opinions derived from her review of Butler Snow’s provided specimens) because those opinions, as described herein, are unreliable.

Dated: April 13, 2017

Respectfully submitted,

By: /s/ John R. Crone
John R. Crone (CO Bar No. 48284)
ANDRUS WAGSTAFF, P.C.
7171 W. Alaska Dr.
Lakewood, CO 80226
Telephone: (303) 276-6360
Fax Phone: (303) 376-6361
John.Crone@andurswagstaff.com
Attorneys for Plaintiffs

² Plaintiffs anticipate Defendants will point out the obvious oddity in Plaintiffs’ argument, that is, Plaintiffs are citing cases in which certain opinions of their own experts were excluded as relying upon an unreliable methodology. Plaintiffs attempted to defend the methodology employed by Drs. Klinge and Iakovlev; however, Plaintiffs were unsuccessful. This does not lead to the conclusion that Defendants’ expert should be allowed to offer opinions based on the same type of methodology this Court has determined is unreliable.

CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

/s/ John R. Crone
John R. Crone (CO Bar No. 48284)
ANDRUS WAGSTAFF, P.C.
7171 W. Alaska Dr.
Lakewood, CO 80226
Telephone: (303) 376-6360
Fax: (303) 376-6361
john.crone@andruswagstaff.com